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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,777	12/21/1999	KEIKO HASEBE	0327-0815-0	4085

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05/14/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/14/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/468,777

Applicant(s)

HASEBE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 11-21 are pending. The Amendment filed April 3, 2002, amended claims 11, 15, 17-19, and added claims 20-21.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed April 3, 2002 (Paper No. 16) to the rejection of claims 11-19 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's amendment filed April 3, 2002 is sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

103 Rejection Maintained

The rejection of claims 11-19 and newly added claims 20-21 under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (EP 0487958) in view of Vanlerberghe et al. (5,985,255) or Young (4,152,272) is MAINTAINED for the reasons set forth in the Office Action mailed January 3, 2002, Paper No. 15, and those found below.

The rejection of claims 11-19 and newly added claims 20-21 under 35 U.S.C. 103(a) as being unpatentable over Dubief et al. (5,679,357) in view of Vanlerberghe et al. (5,985,255) or Young (4,152,272) is MAINTAINED for the reasons set forth in the Office Action mailed January 3, 2002, Paper No. 15, and those found below.

The rejection of claims 11-19 and newly added claims 20-21 under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. (5,476,661) in view of Vanlerberghe et al. (5,985,255) or Young (4,152,272) is MAINTAINED for the reasons set forth in the Office Action mailed January 3, 2002, Paper No. 15, and those found below.

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Applicant argues, "Since the cited references nowhere discloses or suggests the lipid component dispersed as a solid particulate, the present invention is clearly not obvious from these references". This argument is not persuasive, as the preferred amphipathic lipids of formula (1) of the instant invention are disclosed by Nakamura, Pillai, and Dubief. Hence, the amphipathic lipids of formula (1) of the instant invention and those of Nakamura, Pillai, and Dubief must have the same properties. The Examiner respectfully points out that a compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Applicant argues "Nakamura et al. describe a composition in which the amphipathic lipid is present as an emulsion. . .and not a suspension". This argument is not persuasive, as it is not commensurate in scope with the claims, as the claims do not limit the form of the composition to that of a suspension. Regarding the production process of Nakamura et al., the Examiner respectfully points out a) merely modify the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality (*In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955); b) where a product by process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

Applicant argues, "Dubief et al. also describe a composition as an emulsion". This argument is not persuasive, as the recitation "dispersion" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness

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but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, the Examiner respectfully points out that the definition of an emulsion is encompassed by the definition of a dispersion. See Merriam-Webster's Collegiate Dictionary Definitions.

Applicant argues, "Pillai et al. does not disclose any solid particles or particle size whatsoever". This argument is not persuasive. Regarding the solid particles, see the response above. Regarding the particle size, the Examiner respectfully points out a) selection of particle size is not a patentable modification in the absence of unobvious results (*In re Rose*, 105 USPQ 237, CCPA 1955); b) a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 ^SUSPQ 237 (CCPA 1955).

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

The Declaration filed April 3, 2002, is not found persuasive. First, the instant declaration is not commensurate in scope with the instant claims, as independent claim 1 comprises a great number of compounds for the amphipathic lipids, a great number of surfactants, and a great

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percent weight range for the lipids and surfactants, and size range for the lipid. Second, the comparative data is not that of the closest prior art, as the closest prior art discloses amphipathic lipids and not solid lipids. Third, the results are not clear and convincing. It is not clear what the amount of lauryl ether acetate is measuring and how it is related to the instant composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "pseudo-ceramide" in claim 15, is vague and indefinite, as it is not clear what compounds are encompassed by this phrase. The specification does not clearly define this term and one of ordinary skill in the art would not be apprised of all the compounds encompassed by this term.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 8, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200